MAY 0 2 2002

K02283

510(k) Summary

1. **Device Name:** Guidant Balloon Catheter, Models 6714, 6746, 6747

2. **Devices to Which Equivalence is Claimed:** Arrow Balloon Wedge Pressure Catheter with regard to indications for use and design, materials, manufacturing process, packaging process, sterilization process, quality control procedures, and shelf life of the device (pre-enactment device); Cardima VUEPORT Guiding Catheter **(K973298)** with regard to indications for use.

3. **Indication for Use:** The catheter is intended for use in obtaining venograms by occluding the coronary sinus.

4. **Device Description:** The Balloon Catheter is a 6 F occluding catheter with a latex balloon. It is available in three lengths: 60 cm (Model 6746), 90 cm (Model 6714), and 110 cm (Model 6747). All models provide a balloon with an inflation capacity of 1 cc and accept a maximum guide wire diameter of .035 inches. The inflated balloon diameter is 10 mm.

5. **Summary of Technological Characteristics:** This notification concerns a labeling modification to the indications for a currently marketed device. There are no changes to the design, materials, manufacturing process, packaging process, sterilization process, or shelf life of the subject device.

6. **Summary of Substantial Equivalence:** This notification concerns a labeling modification to the indications for the currently marketed device. Substantial equivalence of the proposed indications to the current indications for use are supported by animal GLP and human clinical data. All other aspects of the proposed Guidant Balloon Catheter are identical to the currently marketed Arrow Balloon Wedge Pressure Catheter (pre-enactment device). The indications for use are also substantially equivalent to those of the Cardima VUEPORT Guiding Catheter **(K973298)**.

7. **Testing Data:**

   In Vivo Testing

   An animal study was conducted to evaluate the performance of the Balloon Catheter when used as a conduit for contrast dye administration in the coronary vein. The results of the *in vivo* animal evaluation showed that the performance of the Balloon Catheter is acceptable within the coronary vein. These results support use for the proposed indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2002

Ms. Karen S. Alsop
Pr. Regulatory Affairs Associate
Guidant Corporation
4100 Hamline Avenue N
St. Paul, MN 55112

Re: K021282
Trade Name: LV-1 Hemostasis Valve
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary bypass adaptor, stopcock, manifold fitting
Regulatory Class: Class II (two)
Product Code: DTL

Re: K021283
Trade Name: Guidant Balloon Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II (two)
Product Code: DQO

Re: K021284
Trade Name: EASYTRAK® Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II (two)
Product Code: DQY

Re: K021285
Trade Name: HI-TORQUE® Guide Wires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: April 17, 2002
Received: April 18, 2002

Dear Ms. Alsop:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosures) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include

Human Clinical Testing Data:

The Balloon Catheter was evaluated in a clinical investigation. The function of the Balloon Catheter in this clinical investigation was to aid in obtaining a venogram by occluding the coronary sinus. The results demonstrated that the Balloon Catheter is safe and effective for use in occluding the coronary sinus to obtain a venogram.

8. **Conclusion:** The Balloon Catheter with the modified indication is substantially equivalent to the currently marketed Arrow Balloon Wedge Pressure Catheter (pre-enactment device) with regard to indications for use, design, materials, manufacturing process, packaging process, sterilization process, or shelf life of the subject device. Animal GLP and human clinical data support the modified indication for use. The modified indication for use is also substantially equivalent to the currently marketed Cardima VUEPORT Guiding Catheter (**K973298**).

requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): (To be assigned by FDA) K021283

Device Name: **Guidant Balloon Catheter**

Indications for Use:

The catheter is intended for use in obtaining venograms by occluding the coronary sinus.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter _____
(Per 21 CFR 801.109) (Optional Format 1-1-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021283